Remarks

By the foregoing Amendment, claims 108 and 114 are cancelled and claims 101-107, and 109-111 are amended. New claims 115-124 are presented. Entry of the amendment and favorable consideration thereof is earnestly requested.

The Examiner has rejected the former pending claims 101-114 under 35 U.S.C. §112, first paragraph, as lacking enablement in the specification, and in particular as lacking a teaching of "an effective amount" of CtX, EtX, CtxB, and EtxB to be coadministered with the allergen/antigen, and of the route of administration that is effective for the claimed method. The Examiner has concluded that undue experimentation would be required to practice the claimed invention.

As previously noted, the Declaration of Dr. Neil Williams filed December 16 2002 provides enabling data relating to use of EtxB in studies of animal allergic response modeling human airway diseases. A copy of that Declaration is resubmitted with this response for the convenience of the Examiner.

In addition, a new Declaration Pursuant To 37 C.F.R. § 1.132 provided by the Inventor, Dr. Williams is submitted herewith, along with a report on a study of use of the method of the invention. The study and the report specifically disclose an effective amount of EtxB used in mucosal administration to prevent or treat delayed type hypersensitivity (a Type IV allergy), specifically, hypersensitivity to Hemocyanin, Keyhole Limpet (KLH) and to Chicken Egg White Albumin (OVA). This testing model is useful to analyze Type IV allergies which include reactions such as contact dermatitis as from exposure to poison ivy. In the study, EtxB was used as a therapeutic agent for intranasal administration in mice, and the study provides a basis for determination of an effective amount of EtxB used in mucosal administration humans and other mammals,

and further provides sufficient information to enable mucosal administration of Ctx, Etx, and CtxB in addition to EtxB.

As noted in Applicant's prior response, the Examiner had previously indicated that the specification is enabling "for a method for treating a subject for asthma, allergic rhinitis, atopic eczema, dermatitis, uticaria, or hives comprising administering to the subject an effective amount of an agent wherein the agent is selected from the group consisting of Etx, Ctx, EtxB, and CtxB that bind to GM1 wherein the agent is administered with an allergen and is not coupled to said allergen." (Office Action mailed May 13, 2004, at Page 2, Paragraph 4) and further that the specification is enabling "for a method for treating a subject for asthma comprising administering to the subject an effective amount of an agent wherein the agent is EtxB that binds to GM1." (Office Action mailed July 29, 2003, at Page 3, Paragraph 9). In the most recent action, the Examiner has withdrawn the previous indication of compliance with the enablement requirement, however, Applicant submits that the Examiner's original conclusion was correct, and further that the newly submitted declaration clearly provides enabling support for the amended claims.

In the most recent action, the Examiner has expressed the issue of lack of enablement as the question of the "effective amount" of CtX, EtX, CtxB, and EtxB to be coadministered with the allergen/antigen, and of the route of administration that is effective for the claimed method. It is respectfully submitted that the newly submitted declaration answers both these questions, as it provides enabling data of what is an "effective amount" when used in mucosal administration in accordance with the method of the invention in mice. A person of ordinary skill in the art could readily determine the "effective amount" in humans and other mammals. Further, in the declaration it is specified that the effective amount is administered mucosally, and most specifically by intranasal administration. Clearly, the claims specifying mucosal administration, are fully enabled by the declarations of record and the patent specification. Applicant submits that this

data also supports claims to administration by the other disclosed methods, namely intravenous, intramuscular or and subcutaneous administration. The evidence of record in the application file provides a sufficient basis for a person of ordinary skill in the art to practice the invention.

Accordingly, it is respectfully that the claims are enabled by the submitted declarations in the application file. It is respectfully requested that a Notice of Allowance be issued as to this application.

Respectfully submitted,

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